



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0876]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pretesting of Tobacco Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on pretesting of tobacco communications.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pretesting of Tobacco Communications--(OMB Control Number 0910-0674)--Extension

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 903(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) and to develop stronger health warnings on tobacco packaging as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), it is beneficial for FDA to conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)). In conducting such research, FDA will employ formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences. The information collected will serve two major purposes. First, as formative research it will provide the critical knowledge needed about target audiences. FDA must first understand critical influences on people's decisionmaking process when choosing to use, not use, or quit using tobacco products. In addition to understanding the decisionmaking processes of adults, it is also critical to understand the decisionmaking processes among adolescents (ages 13 to 17), where communications will aim to discourage tobacco use before it starts. Knowledge of these decisionmaking processes will be applied by FDA to help design effective communication strategies, messages, and warning labels. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the

developmental stage. By utilizing appropriate qualitative and quantitative methodologies, FDA will be able to: (1) Better understand characteristics of the target audience--its attitudes, beliefs, and behaviors--and use risk communications; (2) more efficiently and effectively design messages and select formats that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way; (3) determine the best promotion and distribution channels to reach the target audience with appropriate messages; and (4) expend limited program resource dollars wisely and effectively.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Individual In-Depth Interviews	360	1	360	0.75 (45 minutes)	270
General Public Focus Group Interviews	144	1	144	1.5 hours	216
Intercept Interviews: Central Location	600	1	600	0.25 (15 minutes)	150
Intercept Interviews: Telephone	10,000 ²	1	10,000	0.08 (5 minutes)	800
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes)	200
Omnibus Surveys	2,400	1	2,400	0.17 (10 minutes)	408
Total (General Public)	16,304				2,644
Physician Focus Group Interviews	144	1	144	1.5 hours	216
Total (Physician)	144				216
Total (Overall)	16,448				2,860

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Brief interviews with callers to test message concepts and strategies following their call-in request to the FDA Center for Tobacco Products 1-800 number.

The number of respondents to be included in each new pretest will vary, depending on the nature of the material or message being tested and the target audience. However, for

illustrative purposes, table 1 provides examples of the types of studies that may be administered and estimated burden levels that may be incurred during each year of the 3-year period. Time to read, view, or listen to the message being tested is built into the "Hours per Response" figures.

Dated: August 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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